

# Carotid endarterectomy was performed with lower stroke and death rates than carotid artery stenting in the United States in 2003 and 2004

James T. McPhee, MD,<sup>a</sup> Joshua S. Hill, MD, MS,<sup>b</sup> Rocco G. Ciocca, MD,<sup>b</sup> Louis M. Messina, MD,<sup>b</sup> and Mohammad H. Eslami, MD,<sup>b</sup> Worcester, Mass

**Objective:** Although carotid endarterectomy (CEA) is the gold standard for the treatment of carotid artery stenosis, the recent United States Food and Drug Administration approval of carotid artery stenting (CAS) may have led to its widespread use outside of clinical trials and registries. This study compared in-hospital postoperative stroke and mortality rates after CAS and CEA at the national level.

**Methods:** The Nationwide Inpatient Sample (NIS) was queried to identify all patient-discharges that occurred for revascularization of carotid artery stenosis. The *International Classification of Diseases, 9th Revision, Clinical Modification* procedure codes for CEA (38.12), CAS (00.63), and insertion of noncoronary stents (39.50, 39.90) were used in conjunction with the diagnostic codes for carotid artery stenosis, with (433.11) and without (433.10) stroke. Primary outcome measures included in-hospital postoperative stroke and death rates. Multivariate logistic regressions were performed to evaluate independent predictors of postoperative stroke and mortality. Adjustment was made for age, sex, medical comorbidities, admission diagnosis, procedure type, year, and hospital type.

**Results:** During the calendar years 2003 and 2004, an estimated 259,080 carotid revascularization procedures were performed in the United States. CAS had a higher rate of in-hospital postoperative stroke (2.1% vs 0.88%,  $P < .0001$ ) and higher postoperative mortality (1.3% vs 0.39%) than CEA. For asymptomatic patients (92%), the postoperative stroke rate was significantly higher for CAS than CEA (1.8% vs 0.86%,  $P < .0001$ ), but the mortality rate was similar (0.44% vs 0.36%,  $P = .36$ ). For symptomatic patients (8%), the rates for postoperative stroke (4.2% vs 1.1%,  $P < .0001$ ) and mortality (7.5% vs 1.0%,  $P < .0001$ ) were significantly higher after CAS. By multivariate regression, CAS was independently predictive of postoperative stroke (odds ratio [OR], 2.49; 95% confidence interval [CI], 1.91 to 3.25). CAS was also associated with in-hospital postoperative mortality for asymptomatic (OR, 2.37; 95% CI, 1.46 to 3.84) and symptomatic (OR, 2.64; 95% CI, 1.89 to 3.69) patients.

**Conclusions:** As determined from a large representative national sample including the years 2003 and 2004, the in-hospital stroke rate after CAS for asymptomatic patients was twofold higher than after CEA. For symptomatic patients, the respective in-hospital stroke and mortality rates were fourfold and sevenfold higher. These unexpected results indicate that further randomized controlled trials with homogenous symptomatic and asymptomatic patient groups should be performed. (J Vasc Surg 2007;46:1112-8.)

Carotid artery stenting (CAS) was introduced in the early 1990s as a potentially safer, less invasive alternative to carotid endarterectomy (CEA) for the treatment of symptomatic and asymptomatic patients with carotid artery stenosis. Despite its approval by the United States Food and Drug Administration in 2004 for use in symptomatic patients judged to be high risk for CEA,<sup>1</sup> the role of CAS in the management of patients with carotid artery stenosis remains disputed. Although CEA has been shown conclusively to reduce the risk of stroke more than optimal medical therapy alone for patients with symptomatic<sup>2,3</sup> and

asymptomatic<sup>4,5</sup> carotid artery stenosis, similar results from prospective studies of CAS are lacking.

The minimally invasive nature of CAS makes it an appealing treatment option for severe carotid artery stenosis. This fact may lead to increased usage over time<sup>6</sup> beyond its currently approved indications specifically because of varying interpretations of what constitutes “high” surgical risk.

Because high-surgical-risk patients were excluded from the landmark studies that showed CEA is superior to optimal medical therapy alone for symptomatic<sup>2</sup> and asymptomatic<sup>5</sup> carotid artery stenosis, controversy has emerged about the appropriate intervention for this high-risk patient population. This is partly due to the results of certain industry-based trials,<sup>7,8</sup> the designs and outcomes of which have been critiqued by others,<sup>9-12</sup> which have concluded that CAS is not an inferior modality to CEA in terms of composite stroke, death, or myocardial infarction (MI) rates<sup>7,8</sup> despite recent publicly funded randomized trials that have concluded the contrary.<sup>13,14</sup>

From Department of Surgery<sup>a</sup> and the Division of Vascular Surgery,<sup>b</sup> University of Massachusetts Medical School.

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Reprint requests: Mohammad H. Eslami, MD, University of Massachusetts Medical School, Department of Vascular Surgery, 55 Lake Ave N, Worcester, MA 01655 (e-mail: [eslamim@ummhc.org](mailto:eslamim@ummhc.org)).

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The Center for Medicare Services (CMS) recently approved reimbursement for carotid stenting in high-risk symptomatic patients. Because of the conflicting results from nonrandomized trials and the absence of a comparative analysis at the national level of the morbidity and mortality for CAS and CEA, it is difficult for physicians to make definitive recommendations for their patients. For this reason, we undertook a retrospective observational population-based study to determine current in-hospital postprocedural stroke and mortality rates after CAS and CEA in symptomatic and asymptomatic patients in the United States.

## METHODS

To evaluate outcomes for CAS and CEA at the national level, data were obtained from the Nationwide Inpatient Sample (NIS) for the calendar years 2003 and 2004, the most recent years available. The NIS is the most comprehensive database of its kind and includes 100% of abstracted discharge data from a national survey of 20% of all nonfederal acute-care hospitals in the United States.<sup>15</sup> These data are linked to the American Hospital Association's (AHA) annual survey of hospitals by corresponding year to allow analyses of hospital level factors such as bed size, teaching status, and geographic location. The NIS provides a weighting strategy to allow estimates to be made at the national level. Each NIS sample hospital's weight is equal to the number of hospitals it represents during the year. Because 20% of the AHA's hospitals are sampled each year, the given hospital's weight is approximately five.<sup>15</sup> To calculate national estimates, these sample weights are incorporated into the analyses, a technique described by other authors.<sup>16-18</sup> All statistical analyses are based on these survey weights; therefore, all data provided in the results section represent weighted frequencies.

All CAS and CEA procedures performed during the 2-year period were identified by linking the *International Classification of Diseases Ninth Revision, Clinical Modification* (ICD-9CM)<sup>19</sup> procedural codes for CEA and CAS to the appropriate primary diagnostic codes for carotid artery stenosis with and without mention of stroke. Before 2004, because the ICD-9CM procedure code specific to CAS (00.63) did not exist, patients were coded under other less specific procedural codes (Appendix, online only). Carotid stent patients were identified by first querying the database for the procedural codes for "angioplasty or atherectomy of non-coronary vessel (39.50)" and "insertion of non-coronary artery stent (39.90)." These less specific procedure codes were then linked to only those patients with a principal discharge diagnosis of carotid artery stenosis.

To more accurately analyze the primary outcome measures of postoperative stroke and mortality for the two techniques, patients were classified as symptomatic or asymptomatic. If a patient's principal discharge diagnosis was "carotid artery stenosis without mention of stroke" with no accompanying secondary diagnoses for transient ischemic attack (TIA), they were classified as asymptomatic. If a patient's principal discharge diagnosis was "carotid

artery stenosis with stroke" or if there was no mention of stroke but a secondary diagnosis code included that for TIA, patients were classified as symptomatic.

The primary outcome measures for this retrospective study were in-hospital postoperative stroke and death. Postoperative stroke was defined as carrying an ICD-9CM secondary diagnostic code of "post-operative stroke (997.02)." Postoperative death was defined as any death during the same hospital stay regardless of postoperative interval.

All statistical analyses were performed using the advanced survey procedures in the SAS 9.1 software (SAS Institute, Cary, NC). Categorical variables were analyzed by Rao-Scott  $\chi^2$ , and continuous variables were analyzed by survey-weighted analysis of variance (ANOVA), with a value of  $P < .05$  considered statistically significant.

Separate multivariate logistic regressions were performed to determine which factors independently affected postoperative stroke and mortality. The logistic regressions were performed with adjustments made for the covariates of patient age, gender, hospital teaching type, year of procedure, presentation type (symptomatic vs asymptomatic), procedure type (CEA vs CAS), and payer status, as well as the specific comorbid medical conditions of coronary artery disease/previous MI, congestive heart failure, valvular heart disease, diabetes mellitus, chronic lung disease, hypertension, renal failure, and obesity, with the use of comorbidity software previously designed for use with national databases.<sup>20</sup> An interaction term between the treatment method (CAS vs CEA) and symptom status was evaluated and found to be significant for postoperative death; therefore, separate odds ratios (OR) and 95% confidence intervals (CI) of postoperative death are provided according to the presence or absence of symptoms.

## RESULTS

**Patient characteristics.** In the United States during the calendar years 2003 and 2004, an estimated 259,080 patient discharges occurred after CEA or CAS. Of these, 245,045 patients underwent CEA (94.6%) and 14,035 underwent CAS (5.4%). The mean age was 71.1 years [standard error of the mean, 0.08], and 57% were men. Almost all patients (92%) underwent treatment for asymptomatic carotid artery stenoses. Of those that underwent treatment for symptomatic stenoses, 62% were for symptoms of transient ischemic attack (TIA), and 38% were for symptoms of stroke (Table I). The percentage of asymptomatic and symptomatic patients treated at teaching vs nonteaching hospitals was similar. Of those treated at teaching hospitals, 8.1% were symptomatic compared with 7.9% at nonteaching hospitals ( $P = .69$ ).

**Clinical presentation.** On average, patients presenting with symptoms of TIA and stroke were older than the asymptomatic patients (74.8 vs 71.6 years,  $P < .0001$ ). The distribution of comorbid conditions was not uniform by clinical presentation (Fig 1).

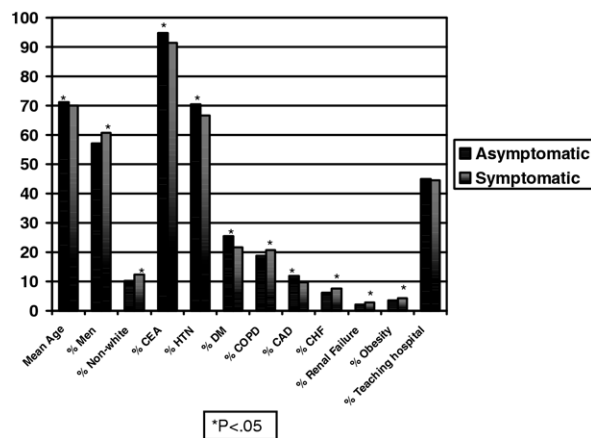
**Univariate analysis of asymptomatic patient characteristics.** The characteristics of the patients undergoing CEA and CAS were comparable in terms of median

**Table I.** Carotid revascularization patient characteristics, 2003 and 2004\*

Factor	Overall, No. (%)	Mortality, %	P
Patients, No.	259,080 (100)	0.44	NA
Age, y			.0002
Mean (SEM)	71.1 (0.08)		
Median (range)	72 (21-97)		
<60	32,287 (13)	0.29	
60-69	73,001 (28)	0.31	
≥70	153,792 (59)	0.53	
Sex			.52
Men	148,455 (57)	0.46	
Women	110,395 (43)	0.42	
Presentation type			<.0001
Asymptomatic	238,390 (92)	0.34	
Symptomatic	20,690 (8)	1.6	
TIA	12,900 (5)	0.43	.96
Stroke	8,003 (3)	3.4	<.0001
Procedure type			<.0001
CEA	245,045 (95)	0.39	
CAS	14,035 (5)	1.3	
Hospital type			.49
Nonteaching	142,352 (55)	0.42	
Teaching	116,728 (45)	0.47	
Payer			.23
Private/Medicare	246,466 (95)	0.49	
Medicaid/self-pay	12,370 (5)	0.29	

CEA, Carotid endarterectomy; CAS, carotid artery stenting; NA, not applicable; SEM, standard error of the mean; TIA, transient ischemic attack.

\*Univariate analysis of overall in-patient mortality is included.



**Fig 1.** This bar graph compares the patient characteristics of those presenting as asymptomatic (black) or symptomatic (grey) carotid artery stenosis, 2003 and 2004. CEA, Carotid endarterectomy; HTN, hypertension; DM, diabetes mellitus; COPD, chronic obstructive pulmonary disease; CAD, coronary artery disease; CHF, congestive heart failure; \* $P < .05$ .

age (72 years for both) and certain comorbid conditions, specifically, diabetes ( $P = .62$ ), coronary artery disease/previous MI ( $P = .94$ ), valvular heart disease ( $P = .44$ ), and obesity ( $P = .15$ ). Patients undergoing CEA had a higher mean age (71.2 vs 70.5 years,  $P < .0001$ ) and a greater prevalence of hypertension ( $P = .011$ ) and chronic lung

disease ( $P = .0004$ ). In contrast, patients undergoing CAS had a higher prevalence of congestive heart failure ( $P < .0001$ ) and renal failure ( $P = .038$ ) than the CEA group and were more likely to be treated at a teaching hospital ( $P < .0001$ ; Table II).

**Univariate analysis of postoperative morbidity and mortality.** For asymptomatic patients with carotid artery stenosis, the postoperative stroke rate was twofold higher after CAS compared with CEA (1.8 vs 0.86%,  $P < .0001$ ), but the crude in-hospital mortality rate after CEA and CAS was similar (.34% vs 0.44%,  $P = .36$ ). The two procedures were similar in terms of postoperative MI (2.0% vs 1.7%,  $P = .31$ ; Table III).

**Univariate analysis of symptomatic patient characteristics.** Patients undergoing CEA had a higher mean age (70.1 vs 68.6 years,  $P < .0001$ ) and a greater prevalence of the comorbid conditions of hypertension (67.3% vs 60.3%,  $P = .023$ ) and chronic lung disease (21.2% vs 14.1%,  $P = .001$ ). In contrast, the CAS patients had a higher prevalence of renal failure (8.6% vs 2.4%,  $P < .0001$ ). The two groups had similar rates of diabetes ( $P = .19$ ), coronary artery disease ( $P = .37$ ), congestive heart failure ( $P = .37$ ), valvular heart disease ( $P = .93$ ), and obesity ( $P = .35$ ; Table II).

**Univariate analysis of postoperative morbidity and mortality.** For symptomatic patients with carotid artery stenosis, the postoperative stroke rate after CAS was nearly fourfold higher than that for CEA (4.2% vs 1.1%,  $P < .0001$ ). Similarly, the CAS patients had a sevenfold higher postoperative mortality rate than the CEA patients (7.5% vs 1.0%,  $P < .0001$ ). The postoperative MI rate was similar for CAS (2.2%) and CEA (2.0%;  $P = .73$ ; Table III).

**Outcomes for octogenarians.** By separate analysis, the percentage of octogenarians in the two procedure groups was similar. Of the open repair group, 19.7% of patients were aged  $\geq 80$  year compared with 18.9% in the endovascular group ( $P = .42$ ). The postoperative stroke rate for octogenarians was increased in the endovascular group compared with the open repair group (3.0% vs 1.0%,  $P < .0001$ ), but the mortality rates were similar (1.2% vs 0.8%,  $P = .19$ ).

**Multivariate analysis of postoperative stroke.** Carotid artery stenting had higher odds of being complicated by postoperative stroke than did CEA (OR, 2.49; 95% CI 1.91 to 3.25). Other variables that independently predicted stroke included older patient age group:  $>70$  vs  $<60$  years (OR, 1.56; 95% CI, 1.10 to 2.25), chronic lung disease (OR, 1.31; 95% CI, 1.07 to 1.61), congestive heart failure (OR, 2.25; 95% CI, 1.70 to 2.98), the presence of symptoms (OR, 1.47; 95% CI, 1.11 to 1.95), and postoperative MI (OR, 2.42; 95% CI, 1.52 to 3.84; Table IV, Fig 2).

**Multivariate analysis of postoperative mortality.** By multivariate logistic regression, which included adjustments for multiple covariates, the performance of CAS was independently predictive of increased postoperative mor-

**Table II.** Patient characteristics for revascularization of asymptomatic and symptomatic carotid artery stenosis

Factor	Overall	Asymptomatic			Symptomatic		
		CEA	CAS	P	CEA	CAS	P
Characteristic							
Overall No.	259,080	226,111	12,278	NA	18,933	1757	NA
Patient age, y							
Mean (SEM)	71.1 (0.08)	71.2 (0.08)	70.5 (0.35)	<.0001	70.1 (0.19)	68.6 (0.71)	<.0001
Median (range)	72 (21-97)	72 (21-97)	72 (24-96)		71 (31-97)	70 (27-92)	
Age groups, %				.039			.20
<60	12.5	11.9	13.9		17.5	20.7	
60-69	28.2	28.2	29.2		26.8	28.2	
≥70	59.4	59.9	56.9		55.7	51.1	
Sex, %				.045			.05
Men	57.4	56.9	59.3		61.1	55.8	
Women	42.6	43.1	40.7		38.9	44.2	
Comorbid conditions, %							
Hypertension	70.2	70.8	66.7	.011	67.3	60.3	.023
Diabetes mellitus	25.1	25.4	25.8	.62	21.4	24.5	.19
Chronic lung disease	18.9	19.0	15.0	.0004	21.3	14.1	.001
CAD/MI	11.6	11.8	11.7	.94	9.8	8.4	.37
CHF	6.4	6.2	9.1	<.0001	7.5	9.8	.13
Valvular disease	6.1	6.0	6.4	.44	6.9	6.8	.93
Renal failure	2.1	2.1	2.7	.038	2.4	8.6	<.0001
Obesity	3.7	3.7	3.0	.15	4.4	3.5	.35
Hospital type, %				<.0001			<.0001
Teaching	45	43.1	81.1		41.6	76.0	
Nonteaching	55	56.9	18.9		58.4	24.0	
Insurance type, %				.002			.017
Private/Medicare	95.2	95.7	92.6		92.5	87.7	
Medicaid/self-pay	4.8	4.3	7.4		7.5	12.3	

CAD, Coronary artery disease; CAS, carotid artery stenting; CEA, carotid endarterectomy; CHF, congestive heart failure; MI, myocardial infarction; NA, not applicable; SEM, standard error of the mean.

**Table III.** Surgical outcomes after carotid endarterectomy and carotid artery stenting for asymptomatic and symptomatic patients

Factor	Overall	Asymptomatic			Symptomatic		
		CEA	CAS	P	CEA	CAS	P
Postoperative, %							
Mortality	0.44	0.34	0.44	.36	1.0	7.5	<.0001
Stroke	0.95	0.86	1.8	<.0001	1.1	4.2	<.0001
MI	1.7	1.7	2.0	.31	2.0	2.2	.73

CAD, Coronary artery disease; CAS, carotid artery stenting; CEA, carotid endarterectomy; MI, myocardial infarction.

tality for asymptomatic patients (OR, 2.37; 95% CI 1.46 to 3.84) and symptomatic patients (OR, 2.64; 95% CI, 1.89 to 3.69; [Table IV](#), [Fig 3](#)). Other independent predictors of in-hospital mortality included presenting with symptoms of TIA or stroke (OR, 4.01; 95% CI, 2.93 to 5.51), older patient age (OR, 1.50; 95% CI, 1.09-2.06), a history of congestive heart failure (OR, 3.74; 95% CI, 2.58 to 5.42), obesity (OR, 2.23; 95% CI, 1.17 to 4.26), and renal failure (OR, 2.50; 95% CI, 1.45 to 4.31). Similarly, certain postoperative complications were strongly associated with in-hospital mortality, including MI (OR, 4.61; 95% CI, 2.62 to 8.12) and stroke (OR, 31.0; 95% CI, 21.5 to 44.7).

## DISCUSSION

This large population-based study has demonstrated that during the calendar years 2003 and 2004, CEA continued to be associated with lower overall rates of postoperative stroke (0.88% vs 2.1%,  $P < .0001$ ) and mortality (0.39% vs 1.3%,  $P < .0001$ ) than CAS. For asymptomatic patients, the mortality rate for CEA and CAS was similar (0.36% vs 0.44%,  $P = .36$ ); however, the postoperative stroke rate of 1.8% for CAS was more than twofold higher than the 0.86% rate for CEA ( $P < .0001$ ). Patients with symptomatic stenoses who underwent CAS had a sevenfold higher postoperative mortality rate (7.5% vs 1.0%,  $P < .0001$ ) and nearly fourfold higher postoperative stroke rate (4.2% vs 1.1%,  $P < .0001$ ) than those undergoing CEA. These observations were confirmed by multivariate logistic regression, which demonstrated that CAS was independently predictive of postoperative mortality and stroke (OR, about 2.4 for both), despite adjustment for comorbid conditions, postoperative complications, and presentation of “symptomatic” vs “asymptomatic” carotid artery stenosis.

Studies with conflicting results have been published comparing outcomes for CAS and CEA. The observations from this administrative study compare favorably with other population-based series limited to in-hospital values, with similar CEA mortality and stroke rates<sup>21</sup> as well as an



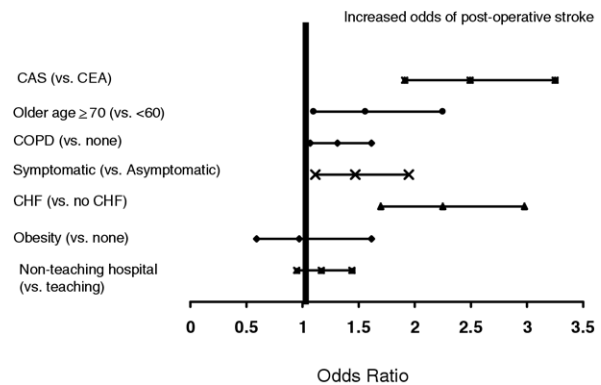
**Table IV.** Multivariate analyses of in-hospital mortality and postprocedural stroke for carotid revascularization, 2003 and 2004

Factor	In-hospital mortality		Postprocedural stroke	
	OR	95% CI	OR	95% CI
Sex				
Men (vs women)	1.08	.82-1.43	1.0	.83-1.20
Age group				
≥70 (vs <60)	1.56	.93-2.62	1.56	1.10-2.25
≥70 (vs 60-69)	1.50	1.09-2.06	1.11	.90-1.35
Insurance type				
Private (vs Medicaid/self-pay)	1.59	.63-4.0	.97	.62-1.53
Co-morbid conditions (vs none)				
Hypertension	.66	.50-.89	.85	.70-1.04
Diabetes	.70	.49-1.02	1.15	.94-1.41
Chronic lung disease	1.30	.93-1.84	1.31	1.07-1.61
CAD/MI	.40	.22-.73	.64	.47-.86
Congestive heart failure	3.74	2.58-5.42	2.25	1.70-2.98
Valvular heart disease	.97	.59-1.58	.74	.50-1.10
Obesity	2.23	1.17-4.26	.97	.59-1.61
Renal failure	2.50	1.45-4.31	.83	.46-1.48
Presentation type				
Symptomatic (vs asymptomatic)	4.01	2.93-5.51	1.47	1.11-1.95
CAS vs CEA				
Asymptomatic	2.37	1.46-3.84	2.49	1.91-3.25
Symptomatic	2.64	1.89-3.69		
Hospital teaching status				
Nonteaching (vs teaching)	.99	.68-1.28	1.17	.95-1.44
Post-op complications (vs none)				
MI	4.61	2.62-8.12	2.42	1.52-3.84
Stroke	31.0	21.5-44.7	NA	NA
Acute renal failure	2.69	0.96-7.56	1.22	.44-3.34

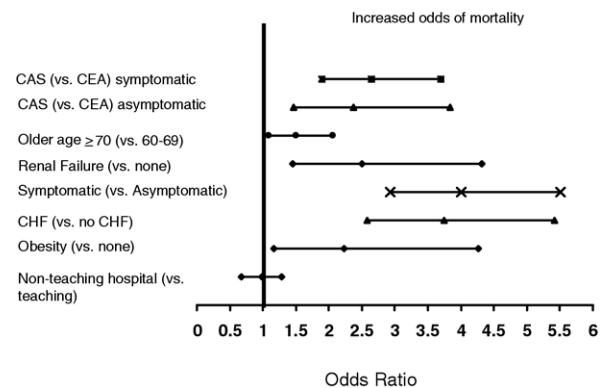
CAD, Coronary artery disease; CAS, carotid artery stenting; CEA, carotid endarterectomy; CI, confidence intervals; MI, myocardial infarction; NA, not applicable; OR, odds ratio.

observed increase in perioperative stroke (2.13% vs 1.28%) and mortality (3% vs 0.5%) rates for CAS compared with CEA at the national level.<sup>6</sup> Unlike the current work, these prior studies did not separately analyze outcomes for symptomatic and asymptomatic patient populations. They were also limited to study years during which CAS was being evaluated in clinical trials and therefore may have represented higher than expected stroke and mortality results than contemporary CAS data.

The observations of the current work also agree with those observed by the authors of the Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) study of 527 subjects, which found a 30-day risk of any stroke or death of 9.6% for CAS vs 3.9% for CEA (relative risk, 2.5).<sup>14</sup> Of note, the EVA-3S study was stopped early owing to concerns of safety and futility in



**Fig 2.** This chart demonstrates the odds ratios with 95% confidence intervals for postoperative stroke after carotid artery revascularization by carotid artery stenting (CAS) or carotid endarterectomy (CEA). CAS was predictive of postoperative stroke by logistic regression. COPD, Chronic obstructive pulmonary disease; CHF, congestive heart failure.



**Fig 3.** The odds ratios with 95% confidence intervals are presented for postoperative death after carotid artery revascularization by carotid artery stenting (CAS) or carotid endarterectomy (CEA). CAS was predictive of postoperative death by logistic regression. CHF, Congestive heart failure.

the CAS arm. The authors of a recent case-control series of 301 subjects similarly concluded that CAS was predictive of 30-day stroke compared with CEA (hazard ratio, 3.9; 95% CI, 1.6 to 9.4,  $P = .0002$ ).<sup>22</sup>

In contrast, several industry-sponsored registries, including the ACCULINK for Revascularization of Carotids in High-Risk patients (ARCHeR) trial and the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE), have concluded that CAS is a noninferior method to CEA in patients at high risk for surgery.<sup>7,8</sup> These latter two studies have been criticized by others because of their methodology, including the heterogeneous population of symptomatic and asymptomatic case-mix,<sup>12</sup> the power of the study,<sup>10</sup> and the validity of a noninferiority study performed on nonrandomized data using a historical control for the surgical arm.<sup>12,23</sup>

The ARCHeR investigators noted a 30-day risk of stroke after CAS of 4.3% in their mostly (76%) asymptomatic patient population, which is similar to the 4.2% postoperative stroke rate observed for symptomatic patients undergoing CAS in the current work. The CAS-associated stroke rate in the ARCHeR study is also substantially higher than the CEA-associated stroke rate of 1.1% in this work and others, which typically report values of 1.3% to 2.1%.<sup>24,25</sup> We note that these previous studies typically report 30-day stroke and mortality rates, whereas the current work is limited to in-hospital rates only, which may reflect falsely lower rates by comparison. Further, the criteria for what constitutes “high-risk” may vary widely based on the methodology of these studies; likewise, individual practitioners may have differing definitions of what constitutes “high risk.”

The current data do not explain why symptomatic patients undergoing CAS had significantly higher rates of mortality and stroke than those undergoing CEA. This study found that the CEA patients were older, and with the exception of renal failure, had either similar (diabetes mellitus, coronary artery disease, congestive heart failure, valvular heart disease, obesity) or more severe (hypertension, chronic obstructive pulmonary disease) comorbidity profiles than the CAS patients. Of note, characteristics such as previous neck surgery, radiation, and carotid vessel morphology, and the use of embolic protection device are not available in this administrative data set.

The asymptomatic patients in this study who underwent CEA and CAS were similar in age (median, 72 years) and evenly matched for prevalence of significant medical comorbid conditions (Table III). Despite this similarity, overall the postoperative stroke rate was significantly greater for the CAS group (1.8% vs 0.86%,  $P < .0001$ ). Of importance, by multivariate logistic regression, which included the variable for symptom status and comorbid conditions, CAS remained independently predictive of postoperative stroke.

The limitations of analyses based on administrative data sets such as the NIS in terms of miscoded and missing data are well known.<sup>26</sup> The analysis in the current study found the percentage of patients treated for asymptomatic carotid artery stenosis (92%) was higher than expected, a fact that warrants further investigation. A patient with a completed stroke who was admitted without an active stroke could conceivably have been misclassified into the asymptomatic cohort. Likewise, if an in-hospital stroke after a procedure was not properly coded as iatrogenic (997.02), the current analysis could have potentially missed or misclassified a percentage of postoperative strokes. It is, however, logical that any potential misclassifications would occur without bias toward any particular procedure group.

In addition, evaluating patient case-mix including the severity of comorbid medical conditions and postoperative complications is difficult to ascertain at the population level.<sup>27</sup> Similarly unknown is the severity of complications such as postoperative stroke and MI. To further compare CEA and CAS patient groups, this clinical data would be

valuable. In this study, however, the variables of greatest interest, including diagnosis type, procedure type performed, and in-hospital mortality are reliably coded in the NIS.

Before October 2004, no dedicated ICD-9CM procedural code for CAS existed, and it was therefore previously coded under other less-specific codes, which may lead to some inaccuracy. The deidentification of patients in the NIS precludes independent coding validation; however, by linking the codes for endovascular angioplasty and stenting with the appropriate diagnostic codes for carotid artery stenosis (primary diagnosis only), the CAS patients should be appropriately classified. This two-step technique to analyze peripheral stenting procedures was previously described by Nowygrod et al.<sup>6</sup>

In addition, in-hospital outcomes, including mortality and stroke, are somewhat limited measures of overall success. Ideally, more long-term information such as 30-day and 1-year follow-up would be used to compare the durability of one procedure vs another; however, they are not available in this data set.

With surgical innovation, less invasive therapies with potential benefits may lead to rapid diffusion of the technology. In the case of CAS, this issue is complicated by the multidisciplinary backgrounds of the physicians performing the procedure, some of whom would not otherwise be providing care for patients with carotid artery occlusive disease, as might be the case for cardiologists. Although the technology for CAS will undoubtedly improve, and one day it may replace CEA as the treatment of choice for some patient populations, this paradigm shift should be predicated on superior short- and long-term results of prospective randomized trials and not technical feasibility and potential benefit.

## CONCLUSION

During the period of this study, 2003 and 2004, within the limitations of data obtained from administrative data sets, CEA in the United States was performed with lower risk of postoperative stroke and death than CAS in symptomatic and asymptomatic patients with carotid artery stenosis. These unexpected differences in observed outcomes are not readily explained by differences in age or the prevalence of medical comorbidities. Further randomized controlled studies with homogenous symptomatic and asymptomatic cohorts should be performed to determine what role CAS will play in the treatment of patients with carotid artery stenosis.

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## AUTHOR CONTRIBUTIONS

Conception and design: JM, JH, LM, ME  
Analysis and interpretation: JM, JH, RC, LM, ME  
Data collection: JM, JH  
Writing the article: JM

Critical revision of the article: LM, RC, ME

Final approval of the article: JM, ME, LM

Statistical analysis: JM, JH

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Overall responsibility: ME

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**APPENDIX (online only).** International Classification of Diseases, 9th Revision, Clinical Modification diagnostic and procedural codes

<i>Diagnosis</i>	<i>Diagnostic code</i>	<i>Procedure</i>	<i>Procedural code</i>
Carotid artery occlusion and stenosis without mention of cerebral infarction	433.10	Carotid endarterectomy	38.12
Carotid artery occlusion and Stenosis with cerebral infarction	433.11	Angioplasty or atherectomy of noncoronary vessel	39.50
Multiple and bilateral carotid artery occlusion and stenosis without mention of cerebral infarction	433.30	Endovascular repair of vessel	39.7
Multiple and bilateral carotid artery occlusion and stenosis with cerebral infarction	433.31	Insertion of noncoronary artery stent or stents	39.90
Transient cerebral ischemia	435.9	Percutaneous insertion of carotid artery stent	00.63
Amaurosis fugax	362.34		